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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,500	11/15/2000	Anthony John Fist	J&J-1763	4831

7590 12/03/2001
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One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

MOONAN, FRANCIS P

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/03/2001

09

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/600,500

Applicant(s)

FIST ET AL.

Examiner

Francis P Moonan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 146 and 50-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-46 and 50-61 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicants' request for amendments to Claims 4-16, 22, 24, 30, 31, 37, 38, 43, 44, 52-55, and 57-60, and cancellation of Claims 47-49 in Paper No. 5 filed on 15 July 2000 is acknowledged.

The requested amendments to Claims 52-55 and 57-60 were incorrect because there was no port of entry in these claims for the recited terms. It appears that the amendments requested for Claims 52-55 and 57-60 should have been requested for Claims 53-56 and 58-61, respectively. Accordingly, the examiner has corrected the amendment of 15 July 2000 and amended claims 53-56 and 58-61. Claims 52 and 57 have not been amended. In addition, the dependent claim numbers recited in the amendments to Claims 53-56 and 58-61 have been corrected as appropriate.

The amendments to Claims 4-16, 22, 24, 30, 31, 37, 38, 43, 44, 53-56, and 58-61 have been entered. The dependencies of Claims 52-61 after amendment is as follows:

Claims 52-56 and 61 depend upon Claim 51 only.

Claims 57-60 depend upon Claim 56 only.

Claims 47-49 have been cancelled.

Claims 1-46 and 50-61 are restricted in the Office Action that follows.

Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-23, 38, 46, and 50, drawn to a stably reproducing *Papaver somnifera* plant with the characteristic of higher (s)-reticuline to morphine content, and a method of making said plant.

Group II, Claims 24-37, drawn to an alkaloid mixture product of a stably reproducing *Papaver somnifera* plant with the characteristic of said plant of higher (S)-reticuline to morphine content.

Group III, Claims 39, 45, 61, drawn to a (S)-reticuline product from a stably reproducing *Papaver somnifera* plant with the characteristic of said plant of higher (S)-reticuline to morphine content .

Group IV, Claims 40-44, drawn to a method of purifying (S)-reticuline from opium from a stably reproducing *Papaver somnifera* plant with the characteristic of said plant of higher (s)-reticuline to morphine content.

Group V, Claims 51-60, drawn to a method of improving the purification of (S)-reticuline from straw of a *Papaver somnifera* plant.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-IV appears to be a stably reproducing *Papaver somnifera* plant. However, a stably reproducing *Papaver somnifera* plant lacks an inventive step and is not novel in view of SZYMANOWSKA et al 1994. Therefore, the technical feature linking the inventions of Groups I-IV does not constitute a special technical feature as defined by PCT Rule 13.2, because it does not define a contribution over the prior art.

The special technical feature of Group I is that it is a plant and a method of making said plant with the characteristic of a higher (s)-reticuline to morphine content.

The special technical feature of Group II is that it is an alkaloid mixture comprising many alkaloids. The special technical feature of Group III is that it is an isolated (S)-reticuline secondary metabolite. The special technical feature of Group IV is that it is a method of purifying (S)-reticuline from opium. The special technical feature of Group V is that it is an improved method of purifying (S)-reticuline from straw.

The inventions of Groups I, II, III, IV, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each have functions and uses not required of the others. The invention of Group I, drawn to a first product and method of making it, has functions and uses not required of the others, for example in the production of poppy seeds for human consumption or commercial bread making. In addition, the mutagenesis steps of Group I are not required by any other Group. The invention of Group II, drawn to a second product, has functions and uses not required of the others, for example in providing a wide range of alkaloid chemicals from its complex mixture as pharmaceuticals that are not derived from (S)-reticuline. In addition, the crude extract of Group II is not required by any other Group. The invention of Group III, drawn to a third product, has functions and uses not required of the others, for example as a substrate for chemical synthesis of a specific subset of alkaloid derivatives. In addition, the purified compound of Group III is not required by any other Group. The invention of Group IV, drawn to a second method, has functions and uses not required of the others, for example in using opium to purify (S)-reticuline. The invention of Group V, drawn to a third

method, has functions and uses not required of the others, for example in providing an improved method to purify (S)-reticuline from straw of genetically unimproved plants.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Therefore, because the groups of inventions are not so linked as to form a single general inventive concept under PCT Rule 13.1, in accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francis Moonan, whose telephone number is (703) 605-1201. The examiner can normally be reached on Monday through Friday 9:00 AM to 5:00 PM (E.S.T.)

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this

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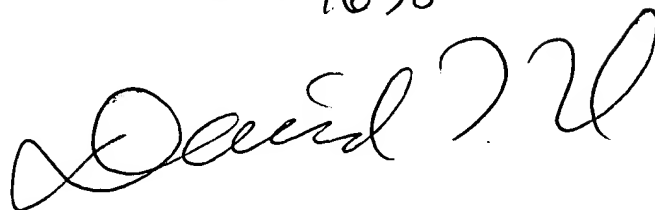
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Group is (703) 308-4315. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Francis Moonan, Ph. D.
29 November 2001

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~-1638

A handwritten signature in cursive script, appearing to read "David T. Fox", written over the printed name and title.